9/23/04 10/016361 C7C

CASE: OP/V-30341B/D1

FILING BY "EXPRESS MAIL" UNDER 37 CFR 1.10

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Express Mail Label Number

Sept. 22, 2004
Date of Deposit

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE PATENT OF

KIS ET AL

U.S. PATENT NO: 6,776,982 B2

ISSUED: AUGUST 17, 2004

FOR: AUTOCLAVABLE PHARMACEUTICAL COMPOSITIONS CONTAINING A CHELATING AGENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Certificate
SEP 28 2004
of Correction

REQUEST FOR CERTIFICATE OF CORRECTION UNDER CFR § 1.322

Sir:

Pursuant to 37 CFR 1.322, it is hereby respectfully requested that a Certificate of Correction be issued for United States Patent 6,776,982 containing the corrections set forth on the appended Form PTO 1050.

The following errors are believed to be attributable to the Patent and Trademark Office as is evident from the table on page 2:

SEP 28 2004

Location and/or Error in Printed Patent	Location of Support in *Specification or Amendment
Title page, Item (*) Notice:, replacement of "This patent is subject to a terminal disclaimer" with "This patent is subject to terminal disclaimers."	Response dated November 15, 2002, page 1 Amendment dated March 4, 2004, page 4

Enclosed is a copy of the terminal disclaimer, dated November 15, 2002 and Amendment including terminal disclaimers, dated March 4, 2003 which show location of support.

Attached is a duplicate of Form PTO 1050, with at least one copy being suitable for printing.

Since the above errors are not attributable to the patentees, therefore, no fee is believed to be necessitated by this Request for Certificate of Correction. However, in the event that a fee is required, the Commissioner is hereby authorized to charge said fee to Deposit Account No. 19-0134 in the name of Novartis Corporation.

Please send the Certificate of Correction to the address currently associated with Customer No. 001095.

Novartis
Corporate Intellectual Property
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Respectfully submitted,

Susan Hess

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Encls.: Form PTO 1050 (2)
Response dated November 15, 2002
Amendment including terminal disclaimers dated March 4, 2004

Date: September 21, 2004

SEP 2 8 2004

Case: OP/V-30341B

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO : 6,776,982 B2
DATED: : August 17, 2004
INVENTOR(S) : KIS ET AL.

It is certified that there is an error in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Title page, Item (*) Notice:, should read:

--This patent is subject to terminal disclaimers.--

MAILING ADDRESS OF SENDER:
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PATENT NO. 6,776,982 B2

FORM PTO-1050

SEP 2 8 2004

Case: OP/V-30341B

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO : 6,776,982 B2
DATED: : August 17, 2004
INVENTOR(S) : KIS ET AL.

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PATENT NO. 6,776,982 B2

FORM PTO-1050

SEP 2 8 2004

CASE OP/V-30341B

FILING BY "EXPRESS MAIL" UNDER 37 CFR 1.10

EV 195227447US
Express Mail Label Number

November 15, 2002
Date of Deposit

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF
KIS ET AL.
APPLICATION NO: 10/016,361
FILED: DECEMBER 10, 2001
FOR: AUTOCLAVABLE PHARMACEUTICAL COMPOSITIONS CONTAINING A CHELATING AGENT

Art Unit: 1615
Examiner: Joynes, Robert M

Assistant Commissioner for Patents
Washington, D.C. 20231

RESPONSE

Sir:

This communication is in response to the Office Action mailed on August 27, 2002. A terminal disclaimer is submitted herewith.

REMARKS

Reconsideration and allowance are respectfully requested.

Claims 1 to 14 are pending and are at issue.

The Examiner has rejected claim 1 to 14 for obviousness-type double patenting over commonly owned U.S. Patent 6,395,756. A terminal disclaimer is submitted herewith, disclaiming the term of any patent that issues from the present application that would extend beyond the expiry of U.S. Patent 6,395,756. It is respectfully submitted that the terminal disclaimer submitted herewith overcomes the ground for the obviousness-type double patenting rejection, and the rejection should be withdrawn.

The Examiner has rejected claims 1 to 14 as obvious under 35 U.S.C. § 103(a) over the disclosure of Yanni, U.S. Patent 5,624,893. Applicants respectfully traverse, and request reconsideration.

At the outset, applicants wish to point out that independent claim 1 uses the transitional language "consisting essentially of". Thus, excluded from the compositions of claims 1 to 6 are any ingredients other than those specifically named, except where those additional ingredients would not materially affect the basic and novel characteristics of the claims.

It is respectfully submitted that the disclosure of Yanni cannot be the basis for a *prima facie* case of obviousness. The fact that a claimed species or subgenus is encompassed by a prior art genus is not sufficient by itself to establish a *prima facie* case of obviousness. (MPEP § 2144.08, citing *In re Baird,* 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994)). The MPEP states that "it is essential that Office personnel find some motivation or suggestion to make the claimed invention in light of the prior art teaching. In the case of a prior art reference disclosing a genus, Office personnel should make findings as to:

(A) the structure of the disclosed prior art genus and that of any expressly described species or subgenus within the genus;

(B) any physical or chemical properties and utilities disclosed for the genus, as well as any suggested limitations on the usefulness of the genus, and any problems alleged to be addressed by the genus;

(C) the predictability of the technology; and

(D) the number of species encompassed by the genus taking into consideration all of the variables possible.

Yanni does not *specifically* disclose even one formulation. All of the Examples of Yanni require the inclusion of an active that must be chosen from one of the 10 neurokinin or bradykinin antagonists, set out at column 10, lines 24 to 42, which would place the compositions outside the scope of the compositions recited in claims 1 to 14. As acknowledged by the Examiner (bottom of page 4 of Office Action) all of the specific formulations of Yanni's Examples also contain disodium edetate (EDTA) which would also place the compositions outside the scope of the claims, as the "consisting essentially of" transitional language does not allow for the inclusion of EDTA, which is specifically disclosed in the present specification to protect ketotifen fumarate from decomposition under autoclaving conditions, i.e., would change a basic characteristic of the claimed compositions.

Yanni lists over 50 steroids, twelve growth factors, over 20 non-steroidal antiinflammatory drugs, five anti-oxidants, seven immunomodulators, ten antiallergics (including ketotifen), 18 antimicrobials, and the neurokinin and bradykinin antagonists mentioned above. Yanni states that any or all of these agents can be used, alone or in combination, to treat corneal haze (column 3, lines 17 to 26). The number of possible formulations that can be made with the agents listed by Yanni numbers in the millions. There is no disclosure or suggestion in Yanni pointing, out of all of the millions of possible formulations, to a formulation consisting essentially of ketotifen hydrogen

fumarate, glycerol, benzalkonium chloride, and water, much less in the specifically recited concentrations, as required by the present claims. As noted above, the only formulations that are more or less specifically suggested are those containing neurokinin or bradykinin antagonists, perhaps in combination with a steroid (see, e.g., claim 2 of Yanni), which is also excluded as an ingredient from the compositions recited in present claims 1 to 14. Accordingly, it is respectfully submitted that Yanni cannot properly be said to suggest the compositions or methods of the present claims, and the rejection of claims 1 to 14 over the disclosure of Yanni should be withdrawn.

The Examiner has also rejected claims 1 to 14 as obvious over the disclosure of Kurasawa et al. (JP 62 277323). Applicants respectfully traverse, and request reconsideration.

The Examiner has stated that "Kurasawa teaches an ophthalmic solution comprising ketotifen fumarate, benzalkonium chloride, glycerol, and water," citing to the Abstract of the Kurasawa application and the text. While the disclosure of Kurasawa might suggest a composition comprising ketotifen fumarate, glycerol, benzalkonium chloride, and water, it is respectfully submitted that Kurasawa cannot properly be said to disclose or suggest the compositions or methods of the claims, and most certainly does not encompass the compositions of the claims, i.e., compositions with a concentration of ketotifen hydrogen fumarate of 0.0345%. In fact, the disclosure of Kurasawa teaches away from making aqueous ophthalmic compositions comprising 0.0345% ketotifen hydrogen fumarate, as required by the present claims.

Applicants respectfully request that the Examiner reconsider the rejection of claims 1 to 14 in light of what Kurasawa teaches, *as a whole*. Kurasawa teaches ophthalmic solutions with a 0.1% concentration of ketotifen fumarate, approximately three times that recited in the present claims. Thus, Kurasawa teaches that a ketotifen fumarate-containing ophthalmic solution should have a concentration of 0.1% to be effective. Further, it is the express purpose of the Kurasawa invention to maintain the concentration of ketotifen fumarate as close to 0.1% as possible. It is very clearly taught that reducing the concentration of ketotifen fumarate below 0.1% is undesirable, and that this end (maintaining the concentration as close to 0.1% as possible) can be best achieved if a polyvalent alcohol or similar agent is used as a tonicity agent, as opposed to an electrolyte tonicity agent.

Thus, Kurasawa teaches away from decreasing the concentration of ketotifen fumarate in an ophthalmic solution below 0.1%, by providing methods to avoid such a decrease. There is certainly nothing in Kurasawa to indicate that a composition with the 0.0345% ketotifen concentration recited in the claims would be useful. When considered with Kurasawa's failure to suggest applicants' claimed specific concentration, it is respectfully submitted that one of ordinary skill in the art would actually have been deterred from even experimenting with ophthalmic compositions that contained

less than 0.1% ketotifen fumarate, much less the three fold lower concentration recited in the present claims.

Applicants submit that the Kurasawa reference being applied by the Examiner is similar to the "Wolf" reference applied by the Examiner in *In re Wiggins*, 397 F.2d 356 (CCPA 1968), submitted herewith. In *Wiggins*, the reference taught a composition comprising the active ingredient of the claimed compositions, but (as with the present claims) in a different dose, with no suggestion by the reference to modify the dose. Like Kurasawa, the Wolf reference had certain disclosures that would discourage those of ordinary skill in the art from experimenting with the dosage of active ingredient (in *Wiggins*, the claimed dose was higher than the disclosed doses). The CCPA found Wiggins's compositions to be not obvious over those disclosed by the cited Wolf reference. It is respectfully submitted that claims 1 to 14 are similarly not obvious in view of the disclosure of Kurasawa.

In light of the above remarks and the terminal disclaimer submitted herewith, it is respectfully submitted that the claims are in condition for allowance, and such action is earnestly solicited.

Respectfully submitted,

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Date: November 15, 2002

urges that defendant's conduct constitutes unfair competition, trademark infringement (15 U.S.C. § 1114(a)), and misleading labeling (15 U.S.C. § 1125 (a)), all of which is causing irreparable harm to the Cutler reputation and trademark, entitling plaintiff to a preliminary injunction.

Universal's position is that it has a right to purchase Cutler relays from the Government and to sell them under plaintiff's trademark. Defendant claims that the old relays meet the current military specifications, and thus it is entitled to relabel them as it has done. In support of this claim defendant has submitted to the court several tests of the H1 relay, conducted by an independent test laboratory, which it claims show the relays meet current standards. The defendant has failed to sustain this claim. The tests required under Military Standard 24140-D1 are approximately thirty in number and probe all the characteristics of the relay under a wide range of environmental conditions. The tests performed for the defendant involved only three of the specific tests required by the specifications and involved only the prevailing climatic conditions. Under these circumstances I am not persuaded that purchasers will not be misled or Cutler-Hammer's reputation harmed.

[1] Defendant is entitled to purchase surplus C-H relays from the Government and resell them under their original labels. Such use of plaintiff's trademark is proper. See Champion Spark Plug Co. v. Sanders, 331 U.S. 125, 73 USPQ 133 (1947). It is also proper for defendant to refer to both Cutler's original parts numbers and the military standards under which the relays have been qualified. Compare Electric Auto-Lite Co. v. P. & D. Mfg. Co., 78 F.2d 700, 26 USPQ 284 (2d Cir. 1935). The vice in defendant's conduct lies in the use of the new labels. These labels plainly represent that the relays are of Cutler origin and meet the current specifications. A purchaser would surely assume that the labels were affixed by Cutler and would rely upon Cutler's reputation for the accuracy of the representation made thereon.

Defendant may or may not be correct when it argues that the relays it is selling do meet current specifications and are not affected by age.[2] But that is beside the point. If Universal wishes to sell the relays backed with its own warranty that they meet present standards it may, perhaps, do so. But in my view, the relabeling of the relays, without Cutler's consent, to indicate they meet current standards constitutes a material alteration of the product and a misuse of plaintiff's trademark. Cf. Bulova Watch Co. v. Allerton Co., 328 F.2d 20, 140 USPQ 440 (7th Cir. 1964); Green v. Electric Vacuum Cleaner Co., 132 F.2d 312, 56 USPQ 127 (6th Cir. 1942); Ingersoll v. Doyle, 247 F. 620 (D. Mass. 1917).

Defendant's labels would also mislead a potential purchaser as to the age of the relays. All of the relays involved here were manufactured by plaintiff prior to February 1961. Defendant's renumbering of them to match the description in plaintiff's current catalogue might well lead a purchaser to conclude that the relays have been recently manufactured. Compare Singer Mfg. Co. v. Briley, 207 F.2d 519, 99 USPQ 303 (5th Cir. 1953); Singer Mfg. Co. v. American Appliance Co., 86 F.Supp. 737 (N.D. Ohio 1919). Universal argues that since the relays are hermetically sealed they do not deteriorate with use. Whether or not this is true, the customer is entitled to base his decision to buy upon an accurate and not a misleading statement of the facts.

[2] A preliminary injunction may only be granted upon a clear showing that plaintiff will probably prevail on the merits and is suffering irreparable harm. Societe Comptoir de L'Industrie v. Alexanders Dept. Stores, Inc., 299 F.2d 33, 132 USPQ 475 (2d Cir. 1962); Zandelin v. Maxwell Bentley Mfg. Co., 197 F.Supp. 608, 131 USPQ 69 (S.D.N.Y. 1961). The preceding discussion demonstrates the clear probability that plaintiff will prevail on the merits. See Polaroid Corp. v. Permarite Corp., 186 F.Supp. 755, 126 USPQ 237 (S.D.N.Y. 1960); Wertheimer v. Milliken, 123 F. Supp. 358, 102 USPQ 292 (S.D.N.Y. 1954); Burlington Mills Corp. v. Roy Fabrics, 91 F.Supp. 39, 85 USPQ 449 (S.D.N.Y. 1950), aff'd, 182 F.2d 1020. 86 USPQ 426 (2d Cir. 1951). It is also clear that defendant's conduct is causing Cutler immediate harm by the threat the mislabeling poses to plaintiff's high reputation in the industry. Defendant is not entitled to have Cutler's reputation bear the burden of defendant's own conclusions as to the fitness of the old relays under the new specifications. Since injuries to reputation are not readily recompensed by money damages the harm caused may well be irreparable. A preliminary injunction is warranted under these circumstances.

The injunctive relief will not, however, be as broad as plaintiff requests. In my view Cutler will be adequately protected by an order enjoining Universal from selling relays with plaintiff's trademark except with the original labels and descriptions. Any further claims made for the relays must be clearly stated to emanate from Universal and not Cutler. Plaintiff will post a $5,000 bond.

The foregoing constitutes my findings of fact and conclusions of law pursuant to Rule 52, F.R.C.P.

Settle order on notice.

[2] Universal has not attempted to qualify the relays under the current military

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Court of Customs and Patent Appeals

In re WIGGINS

No. 7864 Decided June 27, 1968

PATENTS

1. Patentability — New use or function — Composition of matter (§ 51.555)

Were reference to describe or render obvious a composition containing specific amounts of compound, that composition would not appear to differ in any material manner from composition of applicant's claims, no matter to what ultimate use it would be put; in such eventuality, applicant's discovery of specific properties of compound and of a composition containing it could be claimed only as a method or process of using compound or composition in accordance with provisions of 35 U.S.C. 100(b) and 101.—In re Wiggins (CCPA) 158 USPQ 199.

2. Patentability — Invention — In general (§ 51.501)

Rejection under 35 U.S.C. 103 necessarily implies that claimed subject matter is not identically disclosed or described by reference.—In re Wiggins (CCPA) 158 USPQ 199.

3. Court of Customs and Patent Appeals—In general (§ 28.01)

Neither examiner nor Board found that one of ordinary skill would as a matter of course do certain things in carrying out teachings of reference; hence, it is inappropriate that court speculate on what one of ordinary skill might do.—In re Wiggins (CCPA) 158 USPQ 199.

4. Patentability — Invention — In general (§ 51.501)

Reference found that compound was not a "depressant" or "anaesthetic," that it was otherwise "pharmacologically inert," and that it was unsuccessful on oral application; when considered with reference's apparent failure to suggest applicant's claimed dosage amounts, such a triad of basic negative findings, rather than making applicant's discovery obvious, seems to have opposite effect; it would have had general effect of deterring further experimentation; in light of background of subject matter, content of prior art, and differences between it and applicant's claims, court cannot say that applicant's discovery was obvious to one skilled in the art.—In re Wiggins (CCPA) 158 USPQ 199.

Particular patents — Pharmaceutical Preparations

Wiggins, Pharmaceutical Preparations, claims 13 to 15 of application allowed.—In re Wiggins (CCPA) 158 USPQ 199.

Appeal from Board of Appeals of the Patent Office.

Application for patent of Leslie Frederick Wiggins, Serial No. 125,647, filed July 21, 1961; Patent Office Group 120. From decision rejecting claims 13 to 15, applicant appeals. Reversed.

JANES & AESCHLIMANN and CHRISTOPHER AESCHLIMANN (JOHN R. JANES of counsel) all of New York, N. Y., for appellant.

JOSEPH SCHIMMEL (RAYMOND E. MARTIN of counsel) for Commissioner of Patents.

Before WORLEY, Chief Judge, CLARK, Associate Justice*, RICH and SMITH, Associate Judges, and KIRKPATRICK, Judge.**

CLARK, Associate Justice.

This appeal is from the decision of the Board of Appeals which affirmed the examiner's rejection of claims 13-15 in appellant's application[1] as unpatentable under 35 U.S.C. 103 in view of a literature article by Wolf and Braun (Wolf).[2] After careful consideration of "the differences between the prior art and the claims at issue," Graham v. John Deere Co., 383 U.S. 1, 17, 148 USPQ 459, 467 (1966), taken as a whole and specifically in light of the teachings of Wolf, we conclude that appellant's claims comply with the condi-

* Associate Justice retired, Supreme Court of the United States, sitting by designation.

** Senior District Judge, Eastern District of Pennsylvania, sitting by designation.

[1] Serial No. 125,647, filed July 21, 1961, and entitled Pharmaceutical Preparations."

[2] Appearing in Arzneimittel Forschung, Vol. 9, pages 442-3 (July 1959) and abstracted in Chemical Abstracts, Vol. 53, page 20570e (1959).

tions for patentability set forth in section 103 and reverse the decision of the board.

The Application and Claims

The subject matter of the application relates to the discovery that particular chemical compounds—1:3 benzoxazine-2:4-dione and its alkali metal salts—exhibit analgesic activity and alleviate headache pain in humans. According to the specification, a given compound may be administered by placing it in "any of the customary pharmaceutical forms" such as tablets, capsules, powders, pills, ampouled solutions for parenteral administration, suspensions for oral administration and the like. The amounts of the compound which may be administered are governed by its activity and toxicity, the specification stating:

> The toxicity of the compound is such that doses of up to 1000 milligrams may be administered orally say three times a day, whereas its activity is such that doses as low as 10 milligrams each may be employed.

Claims 13-15 read:

> 13. A pharmaceutical preparation in dosage unit form adapted for administration to obtain an analgesic effect, comprising, per dosage unit, an analgesically-effective non-toxic amount within the range from about 10 to about 1000 milligrams of at least one compound selected from the group consisting of 1:3 - benzoxazine-2:4-dione and pharmacologically acceptable alkali metal salts thereof, and a pharmaceutical diluent.
>
> 14. A pharmaceutical preparation in accordance with claim 13 in a form adapted for oral administration.
>
> 15. A pharmaceutical preparation in accordance with claim 14 in the form of a tablet.

Certain other claims, directed to a *method* of obtaining an analgesic effect by administering the compounds recited in claim 13, were allowed by the examiner.

The Prior Art

The Wolf article relied on by the board discloses that, prior to appellant's discovery, the identical compound employed by appellant, 1:3 - benzoxazine-2:4-dione (termed "O_2" by Wolf) was known to protect mice against the effects of X-ray radiation. Wolf describes the method by which he ascertained such activity:

> The investigations were carried out on mice weighing 16-18 g. who were submitted to radiation in groups of

stance was injected in the animals by means of an i.p. [intraperitoneal] administration 10 minutes before the radiation. The dose employed was 150 mg/kg [of mouse weight]. Trials in order to demonstrate a protection after an oral administration were unsuccessful. * * *

It appears Wolf also investigated other properties or activities of "O_2," reporting that:

> In contrast to Nembutal "O_2" has no central depressant or anaesthetic properties. In other respects, also, the substance is pharmacologically inert. * * *

That, in pertinent part, is the scope and content of the prior art reflected in the record before us which, in the board's view, renders the compositions of the claims obvious and frames the issue before us. Subsumed is a determination of the correctness of the board's findings that none of the claim limitations relating to analgesic use, the diluent, dosage unit form, the tablet form and the dosage range are of any patentable significance.

Differences in Subject Matter

Appellant posits four main differences between the subject matter of his claims and the disclosure of Wolf, some of which differences are rather tenuous, others more substantial. Summarized they are:

(1) The claims require the presence of a "pharmaceutical diluent" as part of the compositions, whereas Wolf does not explicitly mention the use of such a diluent or carrier in administering "O_2" to mice.

(2) The claims state that the composition is in a "dosage unit" *form*, a form "adapted for oral administration" and the form of a "tablet," respectively, whereas Wolf, it is said, discloses no particular form in which "O_2" was administered to mice intraperitoneally.

(3) The claims recite the intended *use* of the claimed composition, viz. "to obtain an analgesic effect," whereas Wolf, dealing as he does only with agents protective against X-rays, does not remotely suggest such a use for his disclosed compositions. Indeed, appellant's composition is a "quick acting analgesic when given by the oral route" while Wolf found "O_2" had "no central depressant or anaesthetic properties * * * the substance is pharmacologically inert" and "oral administration was unsuccessful."

(4) The claims require a particular *amount* of active ingredient per dosage unit—"an analgesically-effective non-toxic amount within the range from about 10 to about 1000 milligrams" of the dione or its salts, whereas Wolf neither employs nor suggests the use of such amounts.

With respect to the first difference posed by appellant, the examiner thought that, in view of Wolf's disclosure that "O_2" possesses what the examiner regarded as "pharmaceutical activity," it "would be obvious to include this active pharmaceutical agent with any pharmaceutical diluent," citing In re Rosicky, 47 CCPA 859, 276 F.2d 656, 125 USPQ 341 (1960). The board went one step further, stating that "The combination of the compound and a diluent or vehicle we consider is shown by Wolf." In view of appellant's apparent agreement[3] with the board on the matter, it needs no further discussion.

The remaining three differences between the claims and the prior art are best discussed together. Appellant argues that no composition containing 10-1000 milligrams of "O_2" per dosage unit for use as an analgesic is disclosed or made obvious by Wolf. As an abstract proposition, that argument is undoubtedly true, for it seems most unlikely that one of ordinary skill in the art would consider preparation of a pharmaceutical composition containing the amounts of "O_2" recited in the claims to be obvious for the purpose appellant sets forth, particularly in view of Wolf's statement that "O_2 has no central depressant or anaesthetic properties" and is "pharmacologically inert" in other respects also.

[1] Nevertheless, any agreement by us with that contention is not necessarily dispositive of the issue. More to the point is whether Wolf suggests or makes obvious a composition containing, in addition to a suitable vehicle, 10 to 1000 milligrams of "O_2" per unit dosage for the particular purpose of radiation protection. Were Wolf to describe or render obvious such a composition containing those amounts of "O_2", that composition, of course, would not appear to differ in any material manner from the composition of appellant's claims, no matter to what ultimate use it would be put.[4]

[3] Appellant candidly states:

> The compound is a solid, and it can be presumed (the Patent Office Board of Appeals did) that one skilled in the art would prefer to administer the compound to mice in a carrier or vehicle, since this is a conventional type of composition for intraperitoneal administration.

[4] In such eventuality [illegible]

Here, however, the claimed composition—*certain amounts* of "O_2" plus a diluent—does appear to be new. We say that notwithstanding repeated references by the board as well as the solicitor's brief to appellant's attempt to patent the "old composition" shown by Wolf,[5] for there seems to be no explicit

covery of the analgesic properties of "O_2" and of a composition containing it could properly be claimed only as a method or process of using that compound or composition in accordance with the provisions of 35 U.S.C. 100(b) and 101. See In re Hack, 44 CCPA 954, 245 F.2d 246, 114 USPQ 161 (1957); In re Thuau, 30 CCPA 979, 135 F.2d 344, 57 USPQ 324 (1943), and cases cited therein. As this court stated in In re Lemin, 51 CCPA 942, 326 F.2d 437, 140 USPQ 273, 276 (1964):

> Appellants are clearly correct in demanding that the subject matter as a whole must be considered under 35 U.S.C. 103. *But in applying the statutory test, the differences over the prior art must be more substantial than a statement of the intended use of an old composition.* Counsel for appellants produced a bottle containing a composition at oral argument. It seems to us that the composition in the bottle would be exactly the same whether the user were told to cure pneumonia in animals with it (as in Rothmann) or to promote plant growth with it (as here). The directions on the label will not change the composition of the contents. We therefore fail to find any unobvious distinction in the claim phrase "suitable for promoting growth of plants and for protecting them from damage by parasitic pathogens."
>
> The claim limitation "a parasitic plant pathogen inhibiting and plant growth promoting amount" could be a valid distinction, assuming the art knows what range of amounts is intended by the phrase, *only if it differed from the amount that those having knowledge of the prior art here would employ for the prior art purpose. Here there is no indication that the plant protecting amount is any different from a therapeutic amount that one skilled in the art of Rothman would select.* It, therefore, does not appear that the amount limitation distinguishes the composition from that which would be obvious from the prior art. (Emphasis supplied)

[5] The board stated, somewhat ambiguously we think:

> In substance, claims *13, 14 and 15 merely call for an old compound in an old vehicle or diluent.* We see no patentable significance in the proposed use to which the product will be put as an analgesic. The combination of the compound and a diluent or vehicle we consider is shown by Wolf et al. The intended new use does not make this *old* composition new and patentable. In re Thuau, 30 CCPA 979, * * * 135 F.2d 344, 57 USPQ 324.

description by Wolf of the amounts of "O_2" employed by appellant in his composition. In that regard, Wolf discloses that he employed "O_2" in amounts of 150 milligrams/kilogram of mouse weight for purposes of radiation protection. Since each mouse is said to weigh 16-18 grams, simple calculation establishes that about 2.5 milligrams of "O_2", presumably in some suitable vehicle or carrier, was administered either intraperitoneally or orally to each mouse. A unit dosage containing 2.5 mg "O_2" falls short of the 10-1000 mg amounts recited in the present claims.

We find nothing in Wolf which suggests that he or any other person of ordinary skill in the art would regard the preparation or administration to mice or humans of compositions containing sufficiently greater amounts of "O_2" as to fall within the scope of the appealed claims to be obvious. Nor apparently did the examiner and board—at least their opinions reflect no such finding.[6]

[4] In summary, then, Wolf found that "O_2" was not a "depressant" or "anaesthetic"; that it was otherwise "pharmacologically inert"; and that it was unsuccesful on oral application. When considered with Wolf's apparent failure to suggest appellant's claimed dosage amounts, such a triad of basic negative findings, rather than making appellant's discovery obvious, seems to us to have the direct opposite effect. Indeed, it would have had the general effect of deterring further experimentation. In United States v. Adams, 383 U.S. 39, 148 USPQ 479 (1966), a somewhat similar situation existed in the prior art. There the prior art suggested Adams' combination "was both dangerous and inoperable." Id. at 50, 148 USPQ at 483. Despite that, and other prior art teachings that open circuit batteries which heated in normal use were not practical, and that wet batteries "were successful only when combined with electrolytes detrimental to the use of magnesium," Adams' battery —using the condemned elements—was successful, much to the surprise of the experts. The Court commented:

> These long-accepted factors, when taken together, would, we believe, deter any investigation into such a combination as is used by Adams. This is not to say that one who merely discovers new uses to old inventions by shutting his eyes to their prior disadvantages thereby discovers a patentable innovation. We do say, however, that known disadvantages in old devices which would naturally discourage the search for new inventions may be taken into account in determining obviousness. At 52, 148 USPQ at 484.

Section 103 of the 1952 Patent Act provides that a patent may not be obtained "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." In light of the background of the subject matter here, the content of the prior art and the differences between it and appellant's claims, we cannot say that the discovery of appellant was obvious to one skilled in the art. It was certainly not obvious to Wolf and Braun and no other references are before us. Rather than "an old compound in an old vehicle" as characterized by the board, we find that, while appellant's claimed compositions are based on an old compound, it is obviously a new vehicle on a new thoroughfare.

The decision is *reversed*.

Appellant has discovered a new use for an *old* composition and suitable claims to the method of using it, claims 10, 11 and 12, have been allowed in accordance with 35 U.S.C. 101. The word "process" is defined in 35 U.S.C. 100(b) as including a new use of a *known* composition of matter. However, we do not consider that this *known* composition of matter can become new and patentable by including therewith a statement of intended use or a conventional diluent or by putting it up in dosage unit form as recited in the claims. (Emphasis supplied).

[5] We gather that the board must have meant that a combination of "O_2" and diluent per se was not new. Were the claimed composition in fact described by Wolf in its entirety, there would seem to have been little need for a rejection under § 103. Reliance upon that statutory provision necessarily implies, by its own terms, that the subject matter "is not identically disclosed or described" by Wolf.

[3] [6] Neither the examiner nor board found, for example, that one of ordinary skill in the art, in carrying out the teachings of Wolf, would as a matter of course prepare a composition containing larger amounts of "O_2" in a carrier or vehicle, then divide it into aliquot portions containing 2.5 milligrams "O_2" for administration to each of the 20 or 60 mice in each group tested. Nor did they determine whether such a stock composition would necessarily correspond in any manner to those claimed here. Under the circumstances, we think it inappropriate that we speculate on what one of ordinary skill might or might not do. In re Cofer, 53 CCPA 830, 354 F.2d 634, 148 USPQ 268

Court of Customs and Patent Appeals

SCHMIERER AND VALIN v. NEWTON

No. 7879 Decided June 27, 1968

PATENTS

1. Interference—Burden of proof — Involving applicant and patentee (§ 41.055)

In interference between application and patent, which issued on copending application, applicant (junior party) has burden to establish his case by preponderance of evidence.—Schmierer & Valin v. Newton (CCPA) 158 USPQ 203.

2. Interference — Reduction to practice —Constructive reduction (§ 41.755)

French inventors may not establish under 35 U.S.C. 104 a date of invention by reference to activities in France where their United States application was filed more than one year after corresponding French application, which cannot be relied on for priority; execution of United States application before United States consular officer in France was nothing more than an act "in a foreign country" within meaning of this term in section 104; thus, express wording of section 104 precludes reliance on inventors' activities in France to establish a date of invention, except as to applications filed pursuant to section 119; inventors' failure to comply with section 119 precludes such a reliance.—Schmierer & Valin v. Newton (CCPA) 158 USPQ 203.

3. Interference — Issues determined (§ 41.45)

Question of third-party inventorship may not be raised in interference proceeding.—Schmierer & Valin v. Newton (CCPA) 158 USPQ 203.

4. Interference — Conception of invention (§ 41.10)

In order to prevail, junior party's proofs as to conception must justify conclusion that he possessed a definite and permanent idea of complete and operative invention or that he made invention sufficiently plain to enable one of ordinary skill in the art to understand it.—Schmierer & Valin v. Newton (CCPA) 158 USPQ 203.

Particular patents—Data Processing

3,058,658, Schmierer and Valin, Control Unit for Digital Computing Systems, refused priority against application of Newton, Data Processing Element.—Schmierer & Valin v. Newton (CCPA) 158 USPQ 203.

Appeal from Board of Patent Interferences of the Patent Office.

Patent interference No. 93,980 between Livia C. Schmierer and Jacques H. F. Valin, Patent No. 3,058,658, issued Oct. 16, 1962, on application filed Dec. 22, 1958, and John C. Newton, application, Serial No. 823,988, filed June 30, 1959. From decision awarding priority to Newton, Schmierer and Valin appeal. Affirmed.

KARL F. ROSS, New York, N. Y. (WATSON, COLE, GRINDLE & WATSON, FRANCIS G. COLE, and LAURENCE R. BROWN, all of Washington, D.C., of counsel) for appellants.

DOS T. HATFIELD, Washington, D. C. (EDGAR H. KENT and WILLIS M. ERTMAN, both of Boston, Mass., of counsel) for appellee.

Before WORLEY, Chief Judge, RICH, SMITH, and ALMOND, Associate Judges, and KIRKPATRICK, Judge.*

SMITH, Judge.

This is an appeal by the senior party, Livia C. Schmierer and Jacques H. F. Valin (Schmierer) from a decision of the Board of Patent Interferences,[1] adhered to on reconsideration, awarding priority of the invention set forth in the single count here in issue to appellee, John C. Newton (Newton) the junior party.[2] The sole count originated as claim 1 of Schmierer's United States patent and was copied by Newton for purposes of interference.

[1] Appellants' arguments here raise issues as to whether the facts of record are legally sufficient on the questions of conception, reduction to practice, and diligence on behalf of Newton to support the conclusion of the board. Newton's burden was to establish his case by a preponderance of the evidence. As will be further developed, the facts of record require an affirmance of the decision of the board on the question of priority.

The assignees of the respective parties are Societe Nouvelle d'Electronique of

---

* Senior District Judge, Eastern District of Pennsylvania, sitting by designation.

[1] The board consisted of Messrs. Willner, Boys and Bailey, Examiners of Interferences. Mr. Willner wrote the opinion of the board.

[2] The interference proceedings arose under 35 U.S.C. 135 between an application of John D. Newton, Serial No. 823,988, filed June 30, 1959, entitled "Data Processing Element" and a patent to Livia C. Schmierer and Jacques H. F. Valin, U. S. Patent No. 3,058,658, issued October 16, 1962 entitled "Control Unit for Digital Computing Systems." The patent issued on an application filed in the United

CASE OP/V-30341B

FILING BY "EXPRESS MAIL" UNDER 37 CFR 1.10

EV 195227447US
Express Mail Label Number

November 15, 2002
Date of Deposit

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF
KIS ET AL.
APPLICATION NO: 10/016,361
FILED: DECEMBER 10, 2001
FOR: AUTOCLAVABLE PHARMACEUTICAL COMPOSITIONS CONTAINING A CHELATING AGENT

Art Unit: 1615
Examiner: Joynes, Robert M

Assistant Commissioner for Patents
Washington, D.C. 20231

FEE LETTER

Sir:

Enclosed herewith is a Terminal Disclaimer in the above-identified application.

The Commissioner is hereby authorized to charge the $110 fee under 37 CFR §1.20(d) and any additional fees that may be required to Deposit Account No. 19-0134 in the name of Novartis Corporation. An additional copy of this paper is here enclosed.

Respectfully submitted,

David E. Wildman
Attorney for Applicants
Reg. No. 40,226

Novartis Corporation
Patent and Trademark Dept.
564 Morris Avenue
Summit, NJ 07901-1027
(908) 522-6946
Date: November 15, 2002

CASE OP/V-30341B

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF
KIS ET AL:
APPLICATION NO: 10/016,361
FILED: DECEMBER 10, 2001
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Art Unit: 1615
Examiner: Joynes, Robert M

Assistant Commissioner for Patents
Washington, D.C. 20231

TERMINAL DISCLAIMER

Sir:

Novartis AG, a company organized under the laws of the Swiss Confederation, having a place of business at Schwarzwaldallee 215, Basel, Switzerland 4058, represents that it is the assignee and owner of the entire interest in the above-identified application by virtue of an assignment which is being transmitted for recordation in the United States Patent and Trademark Office concurrently herewith. A copy is attached hereto.

Novartis AG hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the above-identified application which would extend beyond the expiration date of the full statutory term defined in 35 USC §154-156 and §173, as presently shortened by any terminal disclaimer, of prior **Patent No. 6,395,756** issued May 28, 2002. Said Patent No. 6,395,756 is also assigned to Novartis AG by virtue of an assignment which an assignment which was recorded in the United States Patent and Trademark Office on April 11, 2002 at Reel/Frame 0128829/0919.

Novartis AG hereby agrees that any patent granted on the above-identified application shall be enforceable only for and during such period that it and prior Patent No. 6,395,756 are commonly owned. This agreement runs with any patent granted on the above-identified application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, Novartis AG does not disclaim the terminal part of any patent granted on the above-identified application that would extend to the expiration date of the full

statutory term as defined in 35 USC §154-156 and §173 of prior Patent No. 6,395,756, as presently shortened by any terminal disclaimer, in the event that it later: expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR §1.321, has all claims cancelled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

A terminal disclaimer fee under 37 CFR §1.20(d) is included.

Signed this 15th day of November, 2002 by the undersigned attorney of record.

Novartis Corporation
Patent and Trademark Dept.
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Summit, NJ 07901-1027
(908) 522-6946

David E. Wildman
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Reg. No. 40,226

CASE OP/V-30341B

FILING BY "EXPRESS MAIL" UNDER 37 CFR 1.10	
EV365588677US Express Mail Label Number	March 4, 2004 Date of Deposit

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF
KIS ET AL.
APPLICATION NO: 10/016,361
FILED: DECEMBER 10, 2001
FOR: AUTOCLAVABLE PHARMACEUTICAL COMPOSITIONS CONTAINING A CHELATING AGENT

Art Unit: 1615
Examiner: Joynes, Robert M

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

AMENDMENT

Sir:

This is in response to the Office Action mailed on December 8, 2003 having a shortened three month period for response which expires on March 8, 2004. Please amend the application as follows:

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks begin on page 4 of this paper.

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims

Claim 1 (original): An ophthalmic pharmaceutical composition consisting essentially of 0.0345% ketotifen hydrogen fumarate, 2.125% glycerol, 0.01% benzalkonium chloride and water.

Claim 2 (currently amended): [A] The composition according to claim 1 wherein the pH is between about 5.18 and about 5.32.

Claim 3 (currently amended): [A] The composition according to claim 1 wherein the osmolality is about 240 milliosmoles.

Claim 4 (currently amended): [A] The composition according to claim 2 wherein the osmolality is about 240 milliosmoles.

Claims 5-6 (canceled)

Claim 7 (original): A method for making an ophthalmic pharmaceutical composition, comprising admixing the non-aqueous components ketotifen hydrogen fumarate, glycerol, and benzalkonium chloride with water such that a final concentration of the non-aqueous components is 0.0345% ketotifen hydrogen fumarate, 2.125% glycerol, and 0.01% benzalkonium chloride.

Claim 8 (currently amended): [A] The method according to claim 7 wherein the pH of the composition is between about 5.18 and about 5.32.

Claim 9 (currently amended): [A] The method according to claim 7 wherein the osmolality of the composition is about 240 milliosmoles.

Claim 10 (currently amended): [A] The method according to claim 8 wherein the osmolality is about 240 milliosmoles.

Claim 11 (currently amended): [A] The method according to claim 7 wherein the amount of degradation products in said composition [does not exceed] is about 0.03%.

Claim 12 (canceled)

Claim 13 (currently amended): [A] The composition according to claim [12] 1 wherein the amount of degradation products in said composition is about 0.23%.

Claim 14 (currently amended): [A] The composition according to claim [5] 1 wherein the amount of degradation products in said composition is about 0.03%.

REMARKS

Favorable consideration of this application is respectfully requested in view of the foregoing amendments and the following remarks.

Claims 1-5 and 7-14 are pending in the application. Claims 2-4, 8-11,13 and 14 have been amended. Claims 5 and 12 have been canceled without prejudice.

Claims 12 and 13 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. To facilitate prosecution and while not necessarily agreeing with the grounds for the rejection, Claim 12 has been cancelled and Claim 13 has been amended to depend from Claim 1.

In view of the above, withdrawal of the rejection of Claims 12 and 13 under 35 U.S.C. §112, second paragraph, is respectfully requested.

Claims 13 and 14 have been objected to under 37 C.F.R. §1.75(c) as being of improper dependent form for failing to further limit the subject matter of a previous claim. To facilitate prosecution and while not necessarily agreeing with the grounds for the rejection, Claims 13 and 14 have been amended to depend from Claim 1 and Claim 5 has been canceled without prejudice.

In view of the above, withdrawal of the objection of Claims 13 and 14 under 37 C.F.R. §1.75(c) is respectfully requested.

Claims 2-4, 8-11, 13 and 14 have been amended to recite "The composition" and "The method" in place of "A composition" and "A method". Claim 11 has also been amended to recite the term "is about 0.03%" in place of the term does not exceed 0.03%.

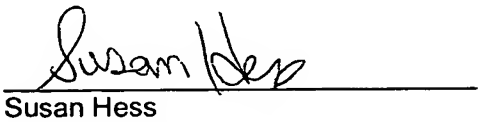
Claims 1-5 and 7-14 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over U.S. Patent 6,455,547. A terminal disclaimer is submitted herewith, disclaiming the term of any patent that issues from the present application that would extend beyond the expiry of U.S. Patent 6,455,547.

In view of the above, withdrawal of the rejection of Claims 1-5 and 7-14 for obviousness-type double patenting is respectfully requested.

To render moot potential claims of obviousness-type double patenting of the claims of the present application by the claims of application serial no. 10/134,795 filed on April 29, 2002 and application serial no. 09/619,349 filed on July 19, 2000, terminal disclaimers are submitted herewith, disclaiming the term of any patent that issues from the present application that would extend beyond the expiry of any patents granted on the 10/134,795 and 09/619,349 applications.

Applicants respectfully request that a timely Notice of Allowance be issued in this case.

Respectfully submitted,



Susan Hess
Attorney for Applicants
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Date: March 4, 2004

PTO/SB/25 (08-03)
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

TERMINAL DISCLAIMER

Docket Number (Optional)
OP/4-30341B

In re Application of: Kis et al.

Application No.: 10/016,361

Filed: December 10, 2001

For: Autoclavable Pharmaceutical Compositions Containing a Chelating Agent

The owner*, Novartis AG, of 100 percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application, which would extend beyond the expiration date of the full statutory term defined in 35 U.S.C. 154 and 173 as shortened by any terminal disclaimer filed prior to the grant of any patent granted on pending second Application Number 09/619,349, filed on July 19, 2000, of any patent on the pending second application. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and any patent granted on the second application are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of any patent granted on the instant application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. 154 and 173 of any patent granted on the second application, as shortened by any terminal disclaimer filed prior to the patent grant, in the event that any such granted patent: expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321, has all claims canceled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term as shortened by any terminal disclaimer filed prior to its grant.

Check either box 1 or 2 below, if appropriate.

1. ☐ For submissions on behalf of an organization (e.g., corporation, partnership, university, government agency, etc.), the undersigned is empowered to act on behalf of the organization.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

2. ☑ The undersigned is an attorney or agent of record.

Susan Hess 3/4/04

Signature Date

Susan Hess

Typed or printed name

(862) 778-7859

Telephone Number

☑ Terminal disclaimer fee under 37 CFR 1.20(d) is included.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

*Statement under 37 CFR 3.73(b) is required if terminal disclaimer is signed by the assignee (owner). Form PTO/SB/96 may be used for making this statement. See MPEP § 324.

PTO/SB/25 (08-03)
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TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A PRIOR PATENT

Docket Number (Optional): OP/4-30341B

In re Application of: Kis et al.

Application No.: 10/016,361

Filed: December 10, 2001

For: Autoclavable Pharmaceutical Compositions Containing a Chelating Agent

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Susan Hess — 3/4/04

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